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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,871	05/07/2001	Osamu Nishimura	2001_0291A	6427

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/29/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,871

Applicant(s)

NISHIMURA ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicants' election of Group I (claims 1-12) without traverse is acknowledged, as are the elected species (growth hormone, glyoxylic acid).

Applicants are urged to either cancel claims 13-16, or else to write these claims so as to fall within the bounds of a proper statutory class of invention (in accordance with U.S. practice).

*

An abstract is required, and does not appear to be present.

*

Claims 1-12 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims make reference to the following:

“the diketone of the optionally oxidized ... methionine”

However, this description is ambiguous, and not really accurate. Following are alternative chemical names for methionine:

2-amino-4-(methylthio)butyric acid;

alpha-amino-*gamma*-methylmercaptobutyric acid;

(S)-2-amino-4-(methylthio)butanoic acid;

gamma-methylthio-*alpha*-aminobutyric acid

What appears to be intended by the “diketone of methionine” is any one of the

following:

2-oxo-4-(methylthio)butyric acid;

alpha-keto-*gamma*-methylmercaptobutyric acid;

2-oxo-4-(methylthio)butanoic acid

gamma-methylthio-*alpha*-ketobutyric acid

Similarly, the corresponding sulfone could be named, e.g., as the following:

2-oxo-4-(methylsulfonyl)butyric acid.

A possible alternative to using the correct chemical terminology would be to retain the current nomenclature system, but to include the reaction scheme (present on page 5) in each of the independent claims.

- The claims are indefinite as to the process steps and endpoint. It is suggested that the phrase - - *for a time and under conditions effective to* - - be used. Following are two options for claim language:

A method for removing 2-oxo-4-(methylthio)butyric acid from the N-terminus of a peptide comprising the step of reacting a peptide bearing an N-terminal 2-oxo-4-(methylthio)butyryl moiety with 3, 4-diaminobenzoic acid in the presence of mixture selected from the group consisting of acetic acid and sodium formate, formic acid and sodium formate, and formic acid and sodium acetate, for a time and under conditions effective to remove the 2-oxo-4-(methylthio)butyric acid group from the N-terminus of said peptide.

A method for removing 2-oxo-4-(methylthio)butyric acid from the N-terminus of a peptide comprising the step of reacting a peptide bearing an N-terminal

2-oxo-4-(methylthio)butyryl moiety with 3, 4-diaminobenzoic acid for a time and under conditions effective to remove the 2-oxo-4-(methylthio)butyric acid group from the N-terminus of said peptide, and wherein said reacting is undertaken in the presence of mixture selected from the group consisting of (a) acetic acid and sodium formate, (b) formic acid and sodium formate, and (c) formic acid and sodium acetate.

- Claim 2 recites that the “the diketone of the optionally oxidized ... methionine” is obtained by reacting a methionine-containing peptide with an alpha diketone. However, this is not accurate. The so-called *alpha*-diketones that are listed are actually *alpha*-keto carboxylic acids.
- In claim 6, the phrase “that is characterized by” is preferably just - - *wherein* - - . See also claim 10.



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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1653